

EXHIBIT 4-b

1 imposes an obligation to do things that promote the
2 advancement of the arts and sciences. That is a separate and
3 independent claim.

4 What we have said is that these rules do not do
5 that. And that they know that the rules don't do that. That
6 standard there is not whether the rules are arbitrary and
7 capricious, it is whether they comply with the Constitution.
8 And, you know, I think that those are areas we would want to
9 explore.

10 We would certainly want to explore--

11 THE COURT: What discovery do you need in order to
12 be able to argue to Judge Cacheris that the rule as passed
13 does not comply with the Constitution?

14 MR. NEALON: You mean, in other words, the patent
15 clause argument?

16 THE COURT: You just said that you thought that the
17 rule as passed was unconstitutional. What discovery do you
18 need in order-- I will put it another way. What do you need
19 that you don't already have in order to be able to make that
20 argument to the District Judge?

21 MR. NEALON: If I could develop evidence that the
22 decision makers who promulgated this regulation, you know,
23 failed to adequately consider whether this regulation as
24 passed and as proposed and promulgated, you know, whether they
25 took into account all the factors that should be considered as

1 to whether it would in fact advance the progression of the
2 arts and sciences as opposed to retard it. I think we should
3 certainly be permitted to explore whether in fact they were
4 aware that it did not do so, but they did so for efficiency
5 reasons.

6 I think that there is deliberative material that is
7 probably going to be outside the scope of the privilege that
8 could be helpful in doing it. And I think if we can show that
9 there was bad faith in trying to circumnavigate around the
10 patent clause by making one statement in the preamble to the
11 rules as to what was permitted and then making another
12 statement that's inconsistent to the OMB and to others, that
13 could be helpful.

14 THE COURT: If you have already got inconsistent
15 statements, why do you need discovery in order to be able to
16 present those inconsistent statements to the District Judge?

17 MR. NEALON: Well, I think that they can be much
18 more effectively presented to the District Judge, you know,
19 both to support an arbitrary and capricious argument and also
20 to support an argument that these officials were acting
21 outside the scope of their constitutional authority.

22 Again, our case theory here is that the PTO have
23 come up with rules that they have essentially tried to portray
24 as procedural when at heart they know that they are
25 substantive. And that the reasons that they have proffered

1 were not proffered in good faith. And that if we have a
2 chance to cross-examine those officials concerning their
3 justifications, we may be able to better expose that than we
4 would if we were limited to simply the face of the record.

5 And as far as the record--

6 THE COURT: What is it about discovery, I am not
7 going to ask this very well, why does discovery affect the
8 issue is this rule procedural or substantive?

9 MR. NEALON: Well, because when we get to the
10 summary judgment phase of this case, okay, the PTO is
11 undoubtedly going to put in affidavits and rely on statements
12 in the record, the presumption of regularity which flows from
13 the fact that the PTO is presumed as sworn officers of the
14 United States to be acting in good faith, they undoubtedly
15 will argue that these rules were passed in good faith and that
16 they are procedural in nature. And that the reasons that they
17 have--

18 THE COURT: The good faith issue may be slightly
19 separate, I am not quite sure yet. But I am trying to focus
20 in the present question on why a rule isn't either procedural
21 or substantive on its face without any need to delve into the
22 process by which the rule was made.

23 MR. NEALON: Well, I mean, they have set forth their
24 supporting reasons in the record as to why they feel these
25 rules are procedural and not substantive. That is certainly

1 one way to look at it. But in terms of trying-- One of the
2 tests is, again, does it have a substantial economic impact on
3 the patent applicant community in terms of trying to decide if
4 this is substantive or not.

5 They have suggested in the proposed justification
6 for these rules that in fact they do not have a substantial
7 impact, that there are safety valves that are legitimate that
8 are built into the process that moves this into the realm of
9 the procedural.

10 We take a different view. We basically say, look,
11 none of that makes any-- The proper justification doesn't
12 make any sense. There is nothing that we can track in the
13 record from whence it comes, I am not sure where you came up
14 with that, but here is what happens in the real world. What
15 you are saying in your preamble to the rules isn't, isn't what
16 is happening in reality.

17 So, I think if we have a chance to cross-examine the
18 people who came up with the rules and came up with the
19 justifications, we have a chance to put on a substantially
20 stronger case because the issue of whether it is procedural or
21 substantive is going to flow in substantial part on what the
22 real world effect is.

23 And what we are saying is the PTO has come up with
24 an explanation as to how they view the world, and we are
25 saying that that is not accurate. And it is not accurate to

1 the effect that it can't even really be asserted in good
2 faith. And we can't track it back to anything in the record
3 to be able to say, wow, this makes sense. And what we see is
4 we see a significant amount of public commentary to the
5 contrary.

6 So, it is a question of a lot of our focus of our
7 claim is on bad faith. And I think on all of these claims,
8 the Constitution, the APA, the RFA, certainly on the RFA bad
9 faith certification, I mean, that is the centerpiece of what
10 we are arguing. And it's a rhetorical question, how could it
11 not help our case if we could develop evidence or admissions
12 through the senior officers who put this proposal together
13 where they are forced to admit that certain of the statements
14 they are making as justifications for this rule which, again,
15 we can't track back to anything in the administrative record,
16 you know, doesn't make sense or they can't support it.

17 So, I think it could be helpful. I mean, we could
18 certainly posit a case where, well, maybe there is enough in
19 the record that you still might be able to make your case, but
20 as an advocate it is my job to try to make the strongest case
21 that I can.

22 And we have a record here, it is a little bit like
23 the Wizard of OZ. If you remember that scene, I don't know if
24 you ever saw the movie, but, you know, essentially everyone
25 walks in--

1 THE COURT: Yes, I did.

2 MR. NEALON: They are told to look up at the screen,
3 which in this case would be the administrative record that has
4 been put together after the fact, and say, look, we want you
5 to look at that.

6 And from our perspective--

7 THE COURT: Pay no attention to that man behind the
8 curtain.

9 MR. NEALON: Right. And we are looking and we are
10 seeing all these feet moving behind the curtain. And we want
11 to have an opportunity, and perhaps a limited opportunity, to
12 probe what was going on behind the curtain because we think we
13 have shown in our papers so many inconsistent statements and
14 inconsistencies that we don't think these rules were proposed
15 in good faith. We think that at a minimum there is a
16 substantial amount of information missing from the record.

17 We think that if a privilege log has to be produced,
18 the record is probably going to be substantially supplemented.

19 And again, maybe these depositions to some extent
20 are premature until we go through that vetting process, but we
21 think that it's going to be very helpful to our case to have a
22 chance to challenge the senior decision makers on some of
23 these issues and inconsistencies in the record, particularly,
24 you know, on the constitutional issue, on the RFA issue where
25 we have to prove bad faith. And I don't know how we go about

1 proving bad faith if those who are creating the record who we
2 say are engaging in bad faith, they are not going to put it on
3 the face of the record.

4 And again, it is not a formal rule making, a closed
5 record. This is a long-standing process that has been going
6 on for a long time. So, we do think that there is a
7 reasonable likelihood that we will develop evidence that will
8 be helpful.

9 Now, on that deliberative process privilege, that
10 would apply in a deposition as well. I mean, it could
11 certainly be asserted on a question by question--

12 THE COURT: That's where it usually comes up.

13 MR. NEALON: Basically.

14 THE COURT: All right, Mr. Nealon, I think I
15 understand your position. Do you have any other points to
16 make before I hear from Mr. Desmarais or any others?

17 MR. NEALON: Well, I would just again direct Your
18 Honor's attention to the actual papers, you know, because we
19 have kind of taken this in bits and pieces here, so I haven't
20 really been able to kind give you a comprehensive soup to nuts
21 overview.

22 We think we have laid out that there are items
23 missing from the record, you know, which call for further
24 review. We certainly think we should be entitled to some
25 discovery on those missing items. And we would certainly be

1 open to pursuing that in any way that the Court deemed
2 appropriate. You know, perhaps interrogatories, a custodian
3 of records deposition. And it may be we need to revisit after
4 we go through that process whether there is something that is
5 turned over that also calls out for depositions.

6 But we certainly think, and I think GSK agrees, that
7 there are items missing from the record that could be very
8 substantial here and we should be permitted to probe it.

9 We do think that we have made a sufficient showing
10 of bad faith that some discovery, and it could certainly be
11 limited, should be allowed into some of those inconsistencies
12 that we have pointed out in our papers.

13 And we are in a difficult position because to some
14 extent we are being told, okay, you have to prove what we
15 withheld. And that's, you know, it is hard to know exactly
16 what may have been withheld or what wasn't withheld. What we
17 can say is we are looking at the record and it is very hard to
18 track anything back.

19 I will give you just one example. There is 129
20 pages in this preamble for the final rules where they go
21 through and address comment after comment after comment which
22 is, you know, a nice thing to do. The problem is, when you go
23 back to the record, you can't find any support for anything
24 that was said. How did they come to those conclusions? What
25 was the reasoning process? Was this arbitrary and capricious?

1 So, by no means are we proposing, you know, to spend
2 the next three or six months deposing every single person in
3 the PTO whoever touched these rules, but we do think it would
4 be appropriate to have a limited opportunity to speak to the
5 senior people who actually put these rules together, and we
6 think kind of did so kind of off in their own parallel
7 universe, a private rule making process and a public rule
8 making process.

9 THE COURT: All right, thank you.

10 MR. NEALON: Thank you.

11 MR. DESMARAIS: Thank you, Your Honor.

12 On the discovery issue, I just have just a brief
13 comment based on the comments so far. GSK has not served any
14 discovery on the PTO and we did not serve deposition notices.
15 So, whether the four served deposition notices are appropriate
16 are between Tafas and the PTO and however Your Honor comes out
17 on that.

18 THE COURT: Yes.

19 MR. DESMARAIS: I would ask though that the Court
20 not issue a blanket ruling on discovery. And here is why. I
21 think we all agree that discovery can be allowed if it is
22 appropriate under the circumstances.

23 For instance, the parties have begun negotiating
24 whether the Patent Office is going give us a privilege log
25 that they have been discussing. They have been asked for a

1 log. Ms. Wetzler was kind enough to write back and say, can
2 you send me authority about whether one is-- So, the parties
3 are still discussing that. And that issue wasn't briefed.

4 Additionally, we have served FOIA requests to get
5 information that supports the administrative record. Those
6 are working its way through the Patent Office. The Patent
7 Office is not asking to quash those by this motion. So, we
8 wouldn't want any order from the Court to do that because the
9 Patent Office even agrees that those are appropriate.

10 When we get the answers back from those FOIA
11 requests depending upon what the answers are, that may lead to
12 targeted discovery that we may need to do at that point.

13 So, my only request would be from GSK that Your
14 Honor not issue any order that would be blanket prohibition,
15 that we take the discovery requests as they come up and
16 address today only whether these four deposition notices are
17 appropriate because there may be as we go forward in the case,
18 remember, we are at the very beginning of the case, as we get
19 the answers to the FOIA requests and as we negotiate with the
20 Patent Office whether they are going to give us a privilege
21 log, there may be targeted discovery that would be relevant.

22 And I find it, you know, today discussing what might
23 be appropriate as we move forward in the case much like it
24 would be an advisory opinion. You know, the record is still
25 developing, we are still moving forward, we still negotiating.